

Translation

## PATENT COOPERATION TREAT



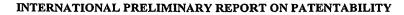
# **PCT**

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

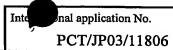
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|---|--|------------------------|---|--|--|
| Applicant's or agent's file reference 03-063-PCT  | FOR FURTHER AC                             | TION                   | See Form PCT/IPEA/416   |  |  |
| International application No. PCT/JP2003/011806   | International filing date 17 September 200 |                        | Priority date (day/month/year) 19 September 2002 (19.09.2002)   |  |  |
| International Patent Classification (IPC) or n<br>C07D 405/12, A61K 31/4525, A  | ational classification and                 | IPC                    | L   |  |  |
| Applicant SUMIT   | TOMO CHEMICAL                              | COMPANY, LII           | MITED   |  |  |
| This report is the international prelin     Authority under Article 35 and trans  |  |                        | International Preliminary Examining 5.  |  |  |
| 2. This REPORT consists of a total of   |  | _                      | heet.   |  |  |
| This report is also accompanied by ANNEXES, comprising:  a. (sent to the applicant and to the International Bureau) a total of sheets, as follows:                        |  |                        |   |  |  |
| a. [] (sent to the applicant and  | to the International Bur                   | reau) a total of       | sheets, as follows:   |  |  |
|   | taining rectifications aut                 |                        | een amended and are the basis of this report ority (see Rule 70.16 and Section 607 of the   |  |  |
|   | osure in the international                 |                        | y considers contain an amendment that goes as indicated in item 4 of Box No. I and the  |  |  |
|   | , contain<br>ndicated in the Supplem       | ning a sequence listir | ope and number of electronic carrier(s)) ng and/or tables related thereto, in computer o Sequence Listing (see Section 802 of the |  |  |
| 4. This report contains indications rela  | ating to the following ite                 | ms:                    |   |  |  |
| Box No. I Basis of the report   |  |                        |   |  |  |
| Box No. II Priority   |  |                        |   |  |  |
| Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |  |                        |   |  |  |
| Box No. IV Lack of unity of invention   |  |                        |   |  |  |
| Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |  |                        |   |  |  |
| Box No. VI Certain documents cited  |  |                        |   |  |  |
| Box No. VII Certain defects in the international application  |  |                        |   |  |  |
| Box No. VIII Certain observations on the international application  |  |                        |   |  |  |
| Date of submission of the demand  |  | Date of completion     | of this report  |  |  |
| 17 February 2004 (17.02.2004)   |  | 18                     | August 2004 (18.08.2004)  |  |  |
| Name and mailing address of the IPEA/JP   |  | Authorized officer     |   |  |  |
| Facsimile No.   |  | Telephone No.          |   |  |  |



International application No.
PCT/JP2003/011806

| Box No. 1         | Basis of the report   |  |   |
|-------------------|---|--|---|
|                   | gard to the language, th  | is report is based on the international application in the langu<br>tem.   | nage in which it was filed, unless  |
|                   |   | translations from the original language into the following anslation furnished for the purpose of:   | language,   |
|                   | international search  | n (under Rules 12.3 and 23.1(b))   |   |
|                   | publication of the i  | nternational application (under Rule 12.4)   |   |
|                   | international prelin  | ninary examination (under Rules 55.2 and/or 55.3)  |   |
|                   |   |  |   |
| furnisi<br>and ar | ed to the receiving Office<br>onot annexed to this rep  | •  |   |
|                   |   | tion as originally filed/furnished   |   |
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|                   | oages   | received by this Authority on  | , as originally filed/furnished   |
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|                   | the claims:   |  | on originally filed/from interd   |
|                   | pages*  | as amended (toge   | , as originally filed/furnished ther with any statement) under Article 19 |
| Ì                 | nages*  | received by this Authority on  |   |
|                   | pages*  | received by this Authority on  |   |
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| 🖰                 | the drawings:   |  | as anisimally filed/farmished   |
|                   | pages*  | received by this Authority on  | , as originally filed/furnished   |
|                   | pages*  | received by this Authority on  |   |
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|                   | a sequence listing and/or   | r any related table(s) - see Supplemental Box Relating to Sec  | quence Listing.   |
|                   |   |  |   |
| 3.                | The amendments have re  | esulted in the cancellation of:  |   |
|                   | the description, pa   | ages   |   |
|                   | the claims, Nos.  |  |   |
|                   | the drawings, shee  | ets/figs   |   |
|                   | the sequence listing  | ng (specify):  |   |
|                   |   | ed to sequence listing (specify):  |   |
| 1                 | - C   |  |   |
| 4.                | made, since they have (Rule 70.2(c)).  the description, p the claims, Nos. the drawings, she the sequence listi | tablished as if (some of) the amendments annexed to this r been considered to go beyond the disclosure as filed, as ages  ets/figs  ng (specify):  et to sequence listing (specify): |   |
| 1                 |   | 1 01-F   |   |
| * If ite          | n 4 applies, some or all o  | of those sheets may be marked "superseded."  |   |





| Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; |
|-----------|--|
|           | citations and explanations supporting such statement   |

| Novelty (N)                   | Claims | 1.7  | YE |
|-------------------------------|--------|------|----|
| 11010105 (11)                 |        | 1-7  |    |
|                               | Claims | 8,9  | NO |
| Inventive step (IS)           | Claims | 1-7  | YE |
|                               | Claims | 8, 9 | NO |
| Industrial applicability (IA) | Claims | 1-9  | YE |
|                               | Claims |      | МО |

2. Citations and explanations (Rule 70.7)

Document 1: EP 223403 A2 (Beecham Group PLC) May 27, 1987

Document 2: EP 812827 A1 (Sumika Fine Chemicals Co., Ltd.) December 17, 1997

Document 1 cited in the international search report (see Claim 1, etc.) states that hemihydrate crystals can be obtained by crystallization or recrystallization of paroxetine hydrochloride from a solvent system that contains water (see page 4, lines 16 to 20).

Document 2 describes a process for obtaining paroxetine hydrochloride by reacting (3S4R)-trans-1-tert-butoxycarbonyl-4-(4-fluorophenyl)-3-[3,4-methylenedioxyphenyl] oxymethyl] piperidine with hydrogen chloride in isopropanol (see Claim 11, etc.)

#### oClaims 1-7

Documents 1 and 2 above neither describe nor suggest the inventions of claims 1-7, and therefore these inventions are novel and involve an inventive step.

### oClaims 8 and 9

Paroxetine hydrochloride hydrate specified by the process of its manufacture is described in the above claims of this application, but the paroxetine hydrochloride hydrate prepared by the process specified in the above claims and the paroxetine hydrochloride prepared by the process described in document 1 are one and the same, and are thus indistinguishable.

As a result, the inventions of claims 8 and 9 lack novelty and an inventive step with respect to document 1 above.

In a written reply dated August 5, 2004, the applicant asserts: "the paroxetine hydrochloride hydrate described in claims 8 and 9 is produced by a process that is different from the process for producing the paroxetine hydrochloride hydrate described in document 1 and can thus be understood to be novel and to involve an inventive step with respect to document 1 (note: typographical error in applicant's assertion corrected)."

However, when an inventive "substance" is identical to a "substance" known from prior art, it cannot be considered to be novel or to involve an inventive step even if the process for producing is different. Because the paroxetine hydrochloride hydrate in the claims of this application and the crystalline paroxetine hydrochloride hydrate described in document 1 cannot be considered to differ as "substances," this examination cannot recognize that the inventions of the above claims of this application have novelty and an inventive step.